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09/117,838	08/12/1998	OLEG LLIICH EPHSTEIN	841/003	4128
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Kaplan Gilman & Pergament LLP 1480 Route 9 North Woodbridge, NJ 07095			EXAMINER	
			PESELEV, ELLI	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/117,838  
Filing Date: August 12, 1998  
Appellant(s): EPHSTEIN, OLEG LLIICH

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Edward D. Pergament  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed May 8, 2009 appealing from the Office action mailed October 8, 2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The summary of claimed subject matter contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

3,134,718	NOBILE	5-1964
3,901,967	COHEN et al	8-1975
4,292,324	JONSSON et al	9-1981
4,839,341	MASSEY et al	6-1989
4,987,127	SIRANY	1-1991
3,032,584	BERGEL et al	5-1962

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 19-21, 23, 25-27 and 45-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,324).

Jonsson et al disclose a method of making a pharmaceutical composition by combining one or more active substances and a method of treatment with said

composition. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure and combining said substances into a single composition would inherently result in the prior art's composition or a composition in which therapeutic dose is so similar to the prior art's dose as to be statistically insignificant.

Claims 29 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen et al (U.S. Patent No. 3,901,967).

Cohen et al disclose a pharmaceutical composition comprising atropine sulfate. The claimed composition comprising atropine and a homeopathic dilution of atropine sulfate is inherent in the prior art's composition.

Claims 30 and 39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sirany et al (U.S. Patent No. 4,987,127).

Sirany discloses a pharmaceutical composition comprising acetylsalicylic acid. The claimed composition comprising acetylsalicylic acid and a homeopathic dilution of acetylsalicylic acid is inherent in the prior art's composition.

Claims 31, 40 and 41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nobile (U.S. Patent No. 3,134,718).

Nobile discloses a pharmaceutical composition comprising Prednizolon. The claimed medication comprising Prednizolon and a homeopathic dilution of Prednizolon is inherent in the prior art's composition.

Claims 32 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Massey et al (U.S. Patent No. 4,839,341).

Massey discloses a pharmaceutical composition comprising insulin. The claimed composition comprising insulin and a homeopathic dilution of insulin is inherent in the prior art's composition.

Claims 33 and 43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,324).

Jonsson et al disclose a pharmaceutical composition comprising zinc. The claimed composition comprising zinc and a homeopathic dilution of zinc is inherent in the prior art's composition.

Claims 43 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bergel et al (U.S. Patent No. 3,032,584, referred to in the Final Office action of 10/08/2008 as Albert Stock John et al).

Bergel et al disclose a pharmaceutical composition comprising Sarcolysin. The claimed composition comprising Sarcolysin and a homeopathic dilution of Sarcolysin is inherent in the prior art's composition.

(10) Response to Argument

A. With respect to the rejections of claims 23, 25-27, 29-34 and 38-45 as anticipated by the prior art references, Appellant contends that the prior art references cited by the Examiner disclose well-known pharmaceutically active compounds present at therapeutic doses but do not disclose a homeopathic dose or a homeopathic dilution of any substance or a combination of a homeopathic dose with a standard dose. This argument has not been found persuasive. The claimed compositions read a composition which combines the same active substance in a therapeutic dose and a homeopathic dilution i.e. the claimed compositions combine the same active substance in different dosages. Such a combination would inherently result in a composition comprising said active compound in a therapeutic dosage. Appellant also contends that the claimed combination and the substances disclosed by the prior art have different properties as shown by the evidence set forth in the declarations by Epstein. The Epstein declarations have been considered but have not been found persuasive. The declarations set forth results of a study but do not provide in comparison form data showing how many experiments were conducted in what result was achieved by administration of an active substance at a therapeutic dosage and what effect was achieved by the claimed combination. Further, it is not clear how different results can be achieved by administering the same compositions i.e. the combination of an active substance at a therapeutic dosage and the same compound in ultra-low dosage

inherently results in a composition comprising an active substance at a therapeutic dosage.

B. With respect to the rejection of claims 17 and 19-21 as anticipated by the prior art references, appellant contends that the prior art of record does not include any disclosure of homeopathic dilutions. This argument has not been found persuasive since the claimed methods encompass nothing more than mixing the same active substance at different dosages resulting in a composition comprising an active substance at a therapeutic dosage.

C. With respect to the rejection of claims 23, 25-27, 29-34 and 38-45 as being obvious over the cited prior art, appellant contends that the prior art of record does not provide any reason to modify a therapeutic dose of a known pharmaceutical substance in the direction of the claimed bipathic combination. This argument has not been found persuasive since a combination of the same active substance at different dosage which results in the composition comprising an active substance in a the therapeutic dosage disclosed by the cited prior art, would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the claimed invention. With respect to the evidence provided in the Epstein declarations, note that is not clear from said declarations how many experiments were performed, what result was achieved by administration of the active substance at a therapeutic dose alone i.e. it cannot be ascertained in the data provided is statistically significant and if the synergism was achieved by the claimed combination.

D. With respect to the rejection of claims 17 and 19-21 as obvious over the cited prior art, appellant contends that the prior art does not disclose admixing a therapeutic dose of an active substance with a homeopathic dilution of said substance. This argument has not been found persuasive since admixing the same active substance in different dosages in order to prepare a composition comprising a known pharmaceutical at a therapeutic dosage would have been *prima facie* obvious to a person having ordinary skill in the art at the time of the claimed invention. With respect to the evidence provided in the Epstein declarations, note that the method claims 17 and 19-21 are not limited to any active substance i.e. the evidence provided is clearly not commensurate with the full scope of the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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